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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,429

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Peter Miller

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EXAMINER

MCCORMICK EWOLDT, SUSAN BETH

ART UNIT

PAPER NUMBER

1661

MAIL DATE

DELIVERY MODE

08/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/823,429

Applicant(s)

MILLER ET AL.

Examiner

S. B. McCormick-Ewoldt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address.--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,10-12,14 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,10-12,14 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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DETAILED ACTION

The amendment of June 13, 2007 is hereby acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims Pending

Applicant has canceled claims 2-9, 13, 15-21 and has added claims 22-24. Claims 1, 10-12, 14 and 22-24 are examined.

Based on the response to the restriction requirement filed July 11, 2005, Applicant elected Group I and the species, creatine monohydrate and dextrose.

Specification

The use of the trademark "Cinnulin PF" has been noted in this application (page 10). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10-12, 14 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In *re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to "cinnamon, extract of cinnamon or derivative thereof." Regarding derivatives, the specification does not define the term, but does indicate that it *includes*, i.e., is not limited to, chalcones, specifically methyl hydroxyl chalcone polymer (i.e. MCHP) (page 7 of the specification). It is equally clear the term encompasses an essentially unlimited genus. Given that the specification discloses only one cinnamon derivative, for example, chalcone, one of skill in the art would conclude that the specification fails to adequately describe the claimed genus.

There is insufficient written description to show that Applicant was in possession of "cinnamon, an extract of cinnamon or derivative thereof" capable of functioning in the claimed invention. Given the disclosure that none of the claimed equivalents might be encompassed for use in the invention of claims, one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus's.

Regarding derivatives, the specification does not define the term, but does indicate that it is not limited to, chalcones, specifically methyl hydroxyl chalcone polymer. It is clear that no examples are disclosed and no common structure or function has been established. Such as in Example 1 of the specification (page 10), Cinnulin PFTM is disclosed in the composition. Accordingly, it is clear that one of skill in the art would conclude that the specification fails to adequately describe the claimed genus.

There is insufficient written description to show that Applicant was in possession of "or derivative thereof." The specification discloses chalcones, specifically methyl hydroxyl chalcone polymer (i.e. MCHP) (page 7 of the specification). The claims however, encompass the use of an essentially unlimited genus of derivatives. Given the limited disclosure and the unlimited number "or derivative thereof," one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, recites the limitation "said cinnamon, extract of cinnamon or derivative thereof" in lines 6-7. There is insufficient antecedent basis for this limitation in the claim.

Claim 1, recites the limitation "the muscle" in line 7: There is insufficient antecedent basis for this limitation in the claim.

In claim 1, the term "enhances" is indefinite as it is not defined in the specification. What encompasses the term "enhance"? Clarification is needed.

In claim 1, in the recitation "a water-soluble extract of cinnamon and creatine monohydrate," the metes and bounds are rendered uncertain because it is unclear if Applicant is claiming an extract of cinnamon and an extract of creatine monohydrate or if Applicant is claiming an extract of cinnamon and further claiming creatine monohydrate. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the claim.

Claim 14, recites the limitation "said supplement" in line 2. There is insufficient antecedent basis for this limitation in the claim.

In claim 14, it is not clear as to what Applicant is meaning in the recitation "56 mmol/kd dry muscle." Clarification is needed.

It is unclear if claim 14 is intended to be a method claim because it is written as a product but has method of use steps. Clarification is needed.

Claim 22, recites the limitation "that fraction of cinnamon" in line 2. There is insufficient antecedent basis for this limitation in the claim.

In claim 22, the recitation "comprised of that fraction of cinnamon" is unclear as to what Applicant is meaning.

In claim 24, it is not clear if "supplement" is part of the dietary supplement or a cinnamon supplement or creatine supplement. Clarification is needed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 10-12, 14 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCabe (US 6,172,114) in view of Greenhaff *et al.* (US 5,968,900), Cheng (US 6,200,569) and Portman (US 6,051,236).

McCabe (US 6,172,114) teaches that creatine is widely distributed in the muscular tissue of the body and that the body-building industry has promoted benefits of creatine supplements as a means of increasing body mass, strength and energy for reducing body fats. Once creatine enters the muscle fibers, it accumulates and stays there for several weeks. The strategy behind creatine supplements is to fill muscles with creatine to capacity and then to take only an amount sufficient to keep creatine stores full (col. 1, lines 11-12, 32-39). McCabe teaches that creatine monohydrate is used along with a carbohydrate. The carbohydrate used is in the amount from 100 mg to 3 g (col. 2, line 6). McCabe also teaches that the creatine is present in the supplement in the amount of about 2 g to about 6 g (i.e. 2,000 mg to 6,000 mg) (col. 2, lines 4-5).

McCabe does not teach that a water-soluble extract of cinnamon is used or that the carbohydrate used is specifically dextrose, maltose, maltodextrin and trehalose or that the water-soluble extract of cinnamon is present in the amount of 0.1 mg to about 100 mg per gram of dietary supplement or that creatine is present in the amount of about 10 mg to about 900 mg per gram of dietary supplement or that the dietary supplement is administered is from about 200 mg to about 500 g per day for a period of 4 to 30 days or where that the water-soluble extract of cinnamon is soluble in 0.1 N acetic acid or that water-soluble extract of cinnamon is present in the amount of 10 mg to 2,000 mg or that water-soluble extract of cinnamon is present in the amount of 2 mg per gram of supplement or that creatine is present in an amount of 78 mg per gram of supplement.

Greenhaff *et al.* (US 5,968,900) teaches a dietary supplement containing creatine and carbohydrates (col. 2, lines 1-3, 10-11 and 53-55). Greenhaff also teaches that creatine has been

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shown to be involved in muscular contraction. Most bodily creatine is present in muscle and that increasing the amount of creatine within muscle favorably affects muscular performance and the amount of work which can be done by the muscle. It is desirable to be able to influence creatine in the body. Glycogen is convertible from and to glucose and athletes endeavor to increase muscle glycogen content before competing in order to enhance muscle performance (col. 1, lines 13-26).

Cheng (US 6,200,569) teaches that water-soluble cinnamon extracts are further extracted with dilute acids such as acetic acid in of 0.1 N acetic acid (col. 3, lines 31-32; col. 4, lines 35-39) to obtain an insulin potentiating agent, which increases insulin activity as measured by increased glucose uptake by cells. Improved insulin activity leads to decreased circulating insulin, which leads to lower blood glucose (col. 3, lines 18-24). Glucose is used in cellular metabolism to produce energy or is converted to glycogen for storage in the muscles (col. 1, lines 29-30). Cheng also teaches that the dry powder can be a single component of cinnamon which amounts ranges from 100 mg-5000 mg (col. 6, lines 63-67; col. 7, line 1).

Portman (US 6,051,236) teaches a nutritional composition for optimizing muscle performance during exercise and for enhancing muscle cell repair and recovery following cessation of exercise. Portman teaches that the nutritional composition includes carbohydrates which replenish muscle glycogen (col. 1, lines 4-9). The carbohydrates include sugars, such as dextrose, maltose and maltodextrins, which are used as an energy source and the replenishment of muscle glycogen supplies (col. 11, lines 16-22). Portman teaches a composition that contains carbohydrates sufficient to stimulate glucose transport, glycogen synthesis and muscle repair (col. 3, lines 43-47).

It would have obvious to one of ordinary skill in the art at the time of invention was made to use creatine with carbohydrates as taught by McCabe and Greenhaff and to modify the dietary supplement by incorporating a water-soluble extract of cinnamon by as taught Cheng. As the prior art teaches, carbohydrates stimulate glucose transport, replenish muscle glycogen and repair muscle and water-soluble extracts of cinnamon improves insulin activity which in turn leads to lower blood glucose. Glucose is used in cellular metabolism to produce energy and is converted to glycogen for storage in muscles. As taught by Greenhaff, glycogen is convertible from and to glucose and athletes endeavor to increase muscle glycogen content before competing

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in order to enhance muscle performance. Creatine is known in the art to be used in nutritional compositions and/or dietary supplements for increasing body mass, strength, and muscle performance. Portman specifically teaches dextrose, maltose and maltodextrins are used in nutritional supplements for optimizing muscle performance. Therefore, by incorporating together creatine monohydrate, a carbohydrate, such as dextrose, maltose, and maltodextrins, and a water-soluble extract of cinnamon, one of ordinary skill in the art would be motivated to form a dietary supplement for the benefit of muscular performance and muscle repair.

Regarding claims 11-12, 14, 23 and 24, the amounts taught by the references show that expectation was known with how much creatine monohydrate, carbohydrate and a water-soluble extract to use to obtain the desired results of the dietary supplement. However, none of the references disclose specifically the amount per gram of dietary supplement. The instantly claimed ranges would be an obvious range for one of ordinary skill in the art to employ based upon the beneficial teachings provided by the cited reference with respect to each of these ingredients having bioactivity- thus incorporating amounts so as to provide such bioactivity would have been obvious to the skilled artisan having the references before him/her as a guide.

Additionally, none of the references teach the dietary supplement in the amounts of about 200 mg to about 500 g per day for a period of 4-30 days to provide and increase in skeletal muscle from about 10 to about 56 mmol/kd dry muscle. However, it would have been obvious to administer the dietary supplement in a wide range of amounts because of the creatine storage capacity varies within a person's body, and is directly related to the person's muscle mass, as well the person's weight and level of exercise. (i.e. a normal person exercising 3x-5x per week as opposed to a professional athlete who would exercise much more vigorously). Therefore, by taking the dietary supplement one would be inherently increasing creatine within the muscle mass.

One would have been motivated to use creatine monohydrate, a water-soluble extract of cinnamon and a carbohydrate because the references teach that creatine favorably affects muscle performance and carbohydrates replenish muscle glycogen. Athletes attempt to increase muscle glycogen to enhance performance. Furthermore, one of ordinary skill in the art would have had a reasonable expectation of success in using creatine monohydrate and a carbohydrate together in a dietary supplement because it has been taught that these ingredients are known to be used in

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nutritional compositions and/or dietary supplements for better muscle performance and muscle repair. A water-soluble extract of cinnamon would be added to the dietary supplement because it is known that cinnamon extracts improves insulin activity which lowers the blood glucose level and glucose is converted to glycogen for storage in the muscles. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Summary

No claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHRISTOPHER R. TATE
PRIMARY EXAMINER